

EXHIBIT 1

(Filed Under Seal)

EXHIBIT 2

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UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

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IN RE BARD IVC FILTERS)
PRODUCTS LIABILITY) NO. MD-15-02641-PHX-DGC
LITIGATION,)
)

DO NOT DISCLOSE
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION
- of -

CHRISTOPHER S. MORRIS, M.D.

taken on behalf of the Plaintiffs on Tuesday,
July 25, 2017, at the Courtyard by Marriott,
25 Cherry Street, Burlington, Vermont,
commencing at 9:08 AM.

VIDEO TECHNICIAN: DEVYN MULHOLLAND
COURT REPORTER: JOHANNA MASSÉ, RMR, CRR

1 you met with Mr. Rogers on -- here in Burlington,
2 Vermont, for four hours?

3 A. Yes.

4 Q. And between July 18 and July 24, did you
5 review any additional materials?

6 A. A few depositions. Several.

7 Q. And did you review anything else?

8 A. No.

9 Q. So the total number of time that you spent
10 preparing for the class action/MDL litigation from May
11 18, 2017, to July 19, 2017, was a total of -- subtotal
12 of 41 hours in that time period?

13 A. Well, just the MDL, yes.

14 Q. And then for the Lisa -- for the expert review
15 of the Lisa Hyde case, you spent another 32 hours?

16 A. Yes.

17 Q. Okay. And then for the expert review of the
18 Carol Kruse case, you spent another 35.5 hours; is that
19 correct?

20 A. Correct.

21 Q. So in the two-month time period, you spent a
22 total of 108.5 hours at \$500 an hour --

23 A. Yes.

24 Q. -- is that correct?

1 So you were paid \$54,250 --

2 A. Yes.

3 Q. -- for that period of time?

4 A. Yes.

5 Q. Then going back in time before that, from
6 February 25 to -- '17, to May 8, '17, that invoice is
7 on Exhibit No. 983; is that correct?

8 A. Yes.

9 Q. Okay. And then that is -- refers to which
10 case?

11 A. This would have been beginning with the class
12 action and then continuing on into the MDL report.

13 Q. Okay. And so there were -- where it's
14 referred to as "Expert Report revision" on February 25,
15 2017; February 26, 2017; March 4, 2017; March 5, 2017,
16 that all has to do with the -- with which report?

17 A. That would have -- those early ones would have
18 been the class action. At that point I didn't even
19 know there was an MDL action, so --

20 Q. And then -- okay. And then there's references
21 to your conversations with both Mr. Rogers and Brandee
22 Kowalzyk; is that correct?

23 A. Yes.

24 Q. And you -- and they were working on the class

1 action, correct?

2 A. As well as the MDL eventually.

3 Q. Okay. And then the Trerotola deposition
4 review, Venbrux deposition review, Lynch deposition
5 review were all the depositions that were taken around
6 that time; is that correct?

7 A. I think they were earlier, but I honestly
8 don't remember if they were part of the class action or
9 the MDL, to tell you the truth.

10 Q. Okay. And then you reviewed the rebuttal
11 reports of Drs. Vogelzang, Eisenberg, and Hertz?

12 A. I'm looking to see where you're --

13 Q. Okay. I'm still on -- on Exhibit 983.

14 MR. ROGERS: It's 4/15/17, Chris.

15 Q. Right. And I'm referring to --

16 A. Oh, 4 -- okay. Yes.

17 Q. Yes. April 15, 2017. You had a call with
18 Mr. Rogers on April 13, 2017, for an hour. Then you
19 looked at those three reports. Then you had another
20 call with him the next day -- or, rather, a week later,
21 April 26, 2017, correct?

22 A. Yes.

23 Q. Then you met with him on May 2, 2017; you had
24 another call with him on May 5, 2017; and then met with

1 him again on May 8, 2017.

2 A. Yes.

3 Q. Okay. On May 8, 2017, you also met with
4 Philip Busman and Jim Rogers in Boston. Who's Philip
5 Busman?

6 A. He -- I know he's also with Nelson Mullins, so
7 he's a lawyer.

8 Q. And then on January 30, 2017, on the next page
9 it refers to a "Medical record and image review of
10 Michael King."

11 A. Yeah.

12 Q. And that has nothing to do with the MDL?

13 A. Right. That's an error. That should not be
14 there.

15 Q. And then on February 1st, 2017, there's a
16 telephone call with Dennis Hom, Kate Helm, and Jim
17 Rogers. Does that have to do with the class action?

18 A. No.

19 Q. Okay. So that's also an error?

20 A. That's an error, yeah.

21 Q. And that should not be there?

22 A. Right.

23 MR. ROGERS: And just for the record, Wendy,
24 that -- I didn't realize that was on there, but that's

1 also a consultation that we probably should have
2 redacted out of here.

3 MS. FLEISHMAN: Okay.

4 MR. ROGERS: So --

5 MS. FLEISHMAN: So let's agree to cull out
6 that reference.

7 MR. ROGERS: That's fine. I just don't want
8 to waive anything by sitting here like a bump on a log.

9 MS. FLEISHMAN: No, no. That's fine. We'll
10 just -- we'll just -- when we -- when we take a break,
11 let's just take that page off of that exhibit.

12 MR. ROGERS: Sounds great. Thank you.

13 MS. FLEISHMAN: Okay?

14 Q. With respect to the -- Exhibit 982, is that --
15 that is an invoice from November 17, 2016, to February
16 21, 2017?

17 A. Yes.

18 Q. Okay. And those are reviews of different
19 medical records of different individuals; is that
20 correct?

21 A. Correct.

22 Q. And -- and also reviews of certain deposition,
23 right?

24 A. Some of the plaintiffs, yes.

1 Q. And in addition to that, there are some
2 imaging reviews?

3 A. Yes.

4 Q. And then you say "Generation of initial draft
5 individual Expert Reports on class representatives:
6 Washington, Tomlin, Holt, Meeks, Barraza, Lester,
7 Messner, Peck, Mosher, Flournay, and Mims."

8 A. Correct.

9 Q. Okay. And that was 20 hours?

10 A. Yes.

11 Q. And did you draft those reports?

12 A. Yes, I did.

13 Q. During that time period?

14 A. Yes.

15 Q. And then you say "Generation of initial draft
16 overall Expert Report." Do you refer -- does that mean
17 the MDL report?

18 A. No. That's the original class action general
19 report.

20 Q. Okay. And then you also then reference
21 another meeting with Nelson Mullins lawyers Jim Rogers
22 and Brandee Kowalzyk.

23 A. Yes.

24 Q. And then you again revise -- okay. So you met

1 them on January 10, 2017, and then a week later you
2 revised the reports.

3 A. Yes.

4 Q. And then again the next -- so January 21, '17,
5 and 22, '17, you spent another nine hours revising
6 those reports?

7 A. Yes.

8 Q. Okay. Then you reviewed Dr. Stavropoulos'
9 deposition --

10 A. Yes.

11 Q. -- at that point?

12 And then after reviewing that deposition, did
13 you add anything to the reports?

14 A. Not based on his deposition, no.

15 Q. And then you met again with the Nelson Mullins
16 lawyers for six hours on February 14?

17 A. Yes.

18 Q. And then you reviewed the depositions of Drs.
19 Hertz, Dr. Bates, and Dr. Eisenberg; is that right?

20 A. Yes.

21 Q. So you spent two and a half hours looking at
22 Dr. Hertz's deposition?

23 A. Yes.

24 Q. You only spent half an hour looking at Dr.

1 Bates'?

2 A. It was very short.

3 Q. And then four hours looking at Dr. Eisenberg's
4 deposition?

5 A. That was a little more thorough, and I had to
6 read that a little more carefully.

7 Q. And then you made revisions to your overall
8 expert report. Was that the -- that was the second
9 report?

10 A. Yes.

11 Q. Okay. And then you had a conference call
12 again, I assume, with Nelson Mullins. It just says
13 "Conference call 2/23/17" for an hour and a half. Do
14 you know who that call was with?

15 A. Can I change my last answer? I think that was
16 still the class action report when I revised it on 2/18
17 and 2/19.

18 Q. So you spent nine hours on 2/18 and 2/19
19 revising that report, and then you spent -- did second
20 revisions of the 11 draft class individual
21 representative reports also on February 19 for another
22 hour --

23 A. Yes.

24 Q. -- is that right?

1 A. Yes.

2 Q. And then you had a call with someone on
3 February 23rd, '17.

4 A. Right.

5 Q. And do you know who that call was with?

6 A. It would have been with Jim Rogers, but I
7 don't -- I don't know why I omitted putting his name in
8 there, but all my calls have been with Jim. Yes. So
9 that would have had to have been Jim Rogers.

10 Q. And how do you keep your time? Do you just
11 write it down and then save it --

12 A. Yeah. I keep it on paper. I have -- and then
13 any event that I do, I just write down exactly how many
14 hours it took me to do that, and so it's a paper
15 recording.

16 Q. And then you provide it to Nelson Mullins and
17 they typed it?

18 A. In an invoice periodically.

19 MR. ROGERS: No.

20 A. No. I typed -- I typed these invoices up.

21 Q. Oh. Oh, okay. So then when you created this
22 list of materials, this -- this list of materials
23 reflects the medical records that you reviewed during
24 that period?

1 A. Yes.

2 Q. And --

3 MR. ROGERS: Here's the official one.

4 THE WITNESS: Okay.

5 MR. ROGERS: Chris, hand me those. I'm just
6 trying to keep all these in order. Thanks.

7 Q. The deposition list at page 12 --

8 A. Okay.

9 Q. -- does not -- is not the same as your
10 invoice.

11 A. I didn't read all those depositions.

12 Q. Okay. So there's -- but, like, on page -- on
13 Exhibit No. 982, right --

14 MR. ROGERS: Hang on. Let me fish it out.

15 Q. Okay. It's the -- it's the invoice 11/17/2016
16 to February 21, 2017.

17 MR. ROGERS: Here you go.

18 THE WITNESS: Okay.

19 Q. Right? So there's a "Medical record review
20 Diane Washington" and then there's a "Deposition review
21 Diane Washington" for three and a half hours.

22 A. Yes.

23 Q. But Diane Washington's deposition's not
24 referenced in your deposition list on page 12 of

1 Exhibit 980.

2 A. These are all experts, of course. I don't
3 know if she's -- I don't know if her deposition's in --

4 MR. ROGERS: Yeah. It's on page 1.

5 THE WITNESS: Page 1.

6 MR. ROGERS: And, Wendy, those aren't
7 specifically identified as depositions, but where it
8 says "Case Specific Materials" Plaintiff, Maria
9 Barraza, et cetera, those are the depositions.

10 MS. FLEISHMAN: Okay.

11 Q. So where it says "Case Specific Materials,"
12 these are the list of depositions that you reviewed for
13 these plaintiffs; is that --

14 A. I'd have to go through my invoice to make sure
15 each one of those had a deposition, but if that -- if
16 they match up, then yes, I read those depositions.

17 Q. Okay. So when you have "Case Specific
18 Materials," what is intended to be included in the
19 case-specific materials in that section of the
20 materials reviewed?

21 A. I think primarily depositions. There was also
22 the original complaint. I read that. And then the
23 second amended class action complaint. I briefly
24 perused the discovery responses. I don't think I

1 really spent much time on the responses.

2 Q. And then you reviewed the medical records --
3 the medical records and radiology imaging are set forth
4 starting at page 1 and go on through page -- up to the
5 end of page 11; is that right?

6 A. Yes.

7 Q. Okay. So those are the imaging records and
8 the medical records; is that right?

9 A. Correct.

10 Q. And then you also have medical records
11 summaries.

12 A. Yes.

13 Q. Okay. Those are not referred to in either
14 list; is that correct?

15 A. Those may be case-specific materials as well,
16 because each patient had a summary that was taken
17 verbatim from the medical records, so I used that as a
18 study guide, and I -- I would classify that as
19 case-specific materials for each patient -- for each
20 plaintiff.

21 Q. Okay. And you brought those with you today?

22 A. No.

23 MR. ROGERS: Yeah. They're here.

24 THE WITNESS: Oh, on thumb drive?

1 MS. FLEISHMAN: They're here?

2 MR. ROGERS: Yeah.

3 THE WITNESS: I'm sorry.

4 MR. ROGERS: Yeah.

5 MS. FLEISHMAN: Okay. So let's mark those, if
6 that's okay.

7 MR. ROGERS: Okay. I don't know where they
8 are.

9 MS. FLEISHMAN: All right. Let's take a short
10 break and just find them, please.

11 THE VIDEOGRAPHER: The time is 10:13 AM.
12 We're off the record.

13 (A recess was taken.)

14 (Deposition Exhibit No. 985 was
15 marked for identification.)

16 THE VIDEOGRAPHER: We're back on the record at
17 10:23 AM.

18 BY MS. FLEISHMAN:

19 Q. Doctor, we've marked as Exhibit --

20 MR. ROTMAN: Cronin. Cronin.

21 MS. FLEISHMAN: I'm sorry?

22 MR. ROGERS: Sorry. Steve was going to be
23 driven crazy until he thought of something, and I know
24 how that feels.

1 A. Yes.

2 Q. What level of certainty did you apply to your
3 opinions?

4 MR. ROGERS: Object to the form.

5 You can respond.

6 A. I don't know really how to answer that
7 question. I think that's more of a legal term, as far
8 as I can tell, but I approached this litigation the
9 same way I practice interventional radiology on a daily
10 basis. I always seek the truth, number one. I use
11 many factors to help render my opinions. That includes
12 first and foremost my personal experience, which I
13 consider large. I also review the medical literature,
14 the pertinent medical literature, of which there's not
15 a lot of Level I or Level II evidence related to IVC
16 filters, unfortunately, and I'm -- I'm part of that
17 problem. I've contributed to the Level III and below
18 evidence as well.

19 But I still use the literature to help me
20 make -- make these decisions. I attend national
21 meetings, talk with colleagues, participate in journal
22 clubs, and honestly rely a lot on the FDA to -- to help
23 make these decisions as well. So there are lots of
24 different factors that go into it.

1 Q. Right. So --

2 A. My -- I approach the litigation using the
3 same -- same methodology, essentially. So I would say
4 a high level of certainty.

5 Q. Right. So I understand your answer was mostly
6 about your methodology, your approach, what things
7 you -- how you approach reaching a decision, and I'm --
8 and I think the last part of your answer where you said
9 "so I would say a high level of certainty," that's
10 really what I was getting after with my question is
11 what level of certainty, and you said a high level of
12 certainty.

13 So my question follow-up on that is, Did
14 you --

15 A. I was going to say the reason I said all those
16 is because if I just relied on a hunch or what my
17 pulmonology colleague told -- told me that had never
18 placed a filter in his life, that methodology would
19 lead me to have less of a high level of certainty.

20 Q. Of course.

21 A. I might have a low -- so that's why I had to
22 give you the background on how I know that I reached a
23 high level of certainty in my opinions.

24 Q. Yes. And so if you were to put a numerical

1 quantification to "high level of certainty," would it
2 be -- what would it be, approximately?

3 MR. ROGERS: Object -- object to the form.

4 A. That is a very difficult question to answer,
5 quant- --

6 Q. You're getting paid \$500 an hour to answer
7 hard questions.

8 A. Well, yeah.

9 MR. ROGERS: Object to the form. That's not
10 the definition --

11 MR. ROTMAN: I'll strike that.

12 MR. ROGERS: -- of what makes a question
13 acceptable.

14 MR. ROTMAN: I'll strike that. I'll strike
15 that.

16 Q. Maybe you can't answer it.

17 A. I mean, you know, the -- so --

18 Q. What level of --

19 A. -- I have to -- I have to answer that
20 difficult question with a difficult answer. And, you
21 know, we were talking on a break a little while ago
22 about memory issues. My -- my benchmark for 100
23 percent certain medical science, so to speak my
24 touchstone, is my brother, who I'm very close to, who's

1 a top ten neuroscience researcher specializing in
2 Alzheimer's and memory disorders, so I gauge that as
3 being 100 percent certain. He has \$50 million in
4 grants. He's the quintessential medical scientist that
5 relies on Level I and Level II evidence. So when I
6 compare his body of work, which I know -- which I've
7 been following my entire life -- again, he's -- you
8 know, he's very close to me and -- and I really respect
9 his degree of scientific validity. When I compare that
10 to the literature that's available regarding IVC
11 filters, there's basically no -- no comparison, so how
12 can I make 100 percent certain opinions based on
13 literature which is less than Level I or Level II
14 evidence?

15 Q. Understood. And -- and so nevertheless, you
16 have reached opinions --

17 A. Yes, I --

18 Q. -- and you had -- and in order to do that, you
19 had to reach a certain point based on your review of
20 the evidence where you had a high level of certainty;
21 that's what you testified. And I'm trying to
22 understand how to understand what you mean by "high
23 level of certainty." So, for example, I asked you for
24 a numerical and I don't -- and I didn't get an answer

1 to that.

2 A. And I can't answer that.

3 Q. And you can't answer that.

4 A. Right.

5 Q. So, you know, would -- would "high level" mean
6 more than 80 percent certain?

7 MR. ROGERS: Object --

8 Q. Let me -- let me suggest that as a starting
9 point.

10 MR. ROGERS: Object to the form. Asked and
11 answered.

12 You can respond.

13 A. And your -- the question is related to all my
14 opinions?

15 Q. Yeah. Your opinions --

16 A. Yeah.

17 Q. -- in this case.

18 A. I would say yes, I'm -- I'm more than a B -- B
19 student, so it would be more than 80 percent, yes. I
20 generally score more than 90 percent.

21 Q. So that's what you generally look for is more
22 than 90 percent certainty for your opinions in this
23 case?

24 A. Generally speaking, yes.

1 literature, that a number of experts in the field based
2 on their own studies of their own patient populations
3 have concluded that the data shows that the -- the
4 length of time that retrievable filters are implanted
5 affects the complication of the retrieval and the
6 likelihood of a complication; you've seen that, right?

7 MR. ROGERS: Object to the form.

8 A. I have seen that stated. I agree with the
9 first part. I'm not convinced about the second part of
10 that.

11 Q. You're not convinced using your level of
12 certainty standard of over 80 percent?

13 MR. ROGERS: Object to the form.

14 A. Because the literature does not support to a
15 high level of certainty that the complication rate
16 increases exponentially. It may increase linearly, and
17 I think you're referring to exponentially, meaning that
18 every additional time frame, that rate of complication
19 increases, not just stays the same.

20 MR. ROTMAN: Did I lose my monitor?

21 MR. LEWIS: Oh, Wendy, can we pass that back?
22 This one right here.

23 MS. FLEISHMAN: Oh, yes. Sure.

24 MR. ROGERS: Hey, Steve, not to interrupt, but

1 we'll never know that they even have a fragment until
2 someone tells them based on a chest x-ray or some kind
3 of scan that they have a fragment there, and in my
4 experience, all of a sudden those patients then do
5 develop symptoms because now they know they have a
6 fragment.

7 Q. But as we established before, asymptomatic
8 fractures and migrations can become life-threatening
9 events?

10 A. Rarely.

11 Q. Rarely. In your opinion, rarely?

12 A. I emphasize rarely.

13 Q. Okay. Now, I want to -- I want to talk about
14 how it could be that -- how it would present, this
15 scenario that you describe where the patient could die
16 from the -- from the needle in the heart, if you would,
17 causing tamponade and bleeding and that -- that series
18 of adverse events.

19 Let's assume a patient is at home with a Bard
20 retrievable filter that was implanted eight years ago
21 and -- this sequence of events in fact happened. And
22 they're home, they're not in the hospital, they're not
23 in a doctor's office, and they wake up dead; in other
24 words, they -- this all happens and they die. Okay?

1 Q. Right. And you don't know as you sit here
2 today whether that's happening all over the place every
3 day or every week in this country and it's not being
4 recognized but filter fractures are killing people and
5 they're dying at home and nobody's connecting it to the
6 filter?

7 MR. ROGERS: Object to -- object to the form
8 and foundation.

9 You can respond.

10 Q. Did you just laugh?

11 A. Well, I'm trying to think of the scenario. I
12 mean, that -- people die from many different reasons.
13 That's, like, a negative question you're asking me, so
14 how can I prove a negative if there's no evidence on a
15 negative?

16 Q. You can just answer my question, which was,
17 You don't know as you sit here today whether this is
18 happening frequently and not being detected?

19 A. I don't know that --

20 MR. ROGERS: Object to the form.

21 Q. Right?

22 A. I don't know that it is; I don't know that it
23 isn't.

24 Q. Right. And so you cannot say to a reasonable

1 degree of scientific certainty that this event is rare
2 unless you know the answer to the question of whether
3 it's recognized when it happens on a regular basis,
4 right?

5 MR. ROGERS: Object to the form.

6 A. It's speculation.

7 Q. You don't know if it's rare or not, do you?

8 MR. ROGERS: Object to the form.

9 A. I -- that's really difficult to answer because
10 we know from some of these observational studies that
11 have filter fragments in their chest, the vast majority
12 of them are asymptomatic and they're not reporting
13 large numbers of deaths in their patient population,
14 so --

15 Q. Now, in the middle paragraph of this Hull
16 paper, you see that in addition to evaluating
17 whether -- the condition of the filter, they were
18 looking at these fractured filter parts under a
19 scanning electron microscope, right?

20 A. Yes.

21 Q. And they did so and they made a determination
22 that it looked like to them bending fatigue fractures,
23 right?

24 A. That's what they say, yes.

1 certainty you have regarding an opinion?

2 A. No.

3 Q. And did you have difficulty doing that?

4 A. Yeah. That was a little bit difficult for me
5 to answer. I have -- I have testified as an expert
6 witness previously, and I was asked sort of a similar
7 question, and the term was "more likely than not," so I
8 always -- I always thought that that was, you know, 90
9 plus percent or greater, and it turns out by legal
10 definition that's 51 percent versus 49 percent, so
11 that's something I learned at that time, but I think
12 that's the only other time I've encountered a question
13 like that.

14 Q. So you're familiar with that medical-legal
15 concept of opinion needing to be stated to a reasonable
16 degree of medical certainty?

17 A. Yes.

18 Q. And is that what you were talking about that
19 you're interpreting as being more than 50 percent?

20 A. Yeah. 51 percent.

21 Q. And so are all the opinions that you stated in
22 your report and in your deposition in this case, are
23 those all held to a reasonable degree of medical
24 certainty?

EXHIBIT 3

(Filed Under Seal)

EXHIBIT 4

Do Not Disclose - Subject to Further Confidentiality Review

Page 1

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

No. MD-15-02641-PHX-DGC

IN RE BARD IVC FILTERS PRODUCTS

LIABILITY LITIGATION

DO NOT DISCLOSE

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF CLEMENT J. GRASSI, MD

Thursday, June 15, 2017

9:24 a.m.

Held At:

Nelson Mullins Riley & Scarborough LLP

One Post Office Square

Boston, Massachusetts

REPORTED BY:

Maureen O'Connor Pollard, RMR, CLR, CSR

1 and I have to try to think back over years of
2 working with them, I have not retrieved a Bard
3 recent device where I've seen a fracture, no.

4 THE VIDEOGRAPHER: Dr. Grassi, I'm
5 getting some noise from the wire.

6 THE WITNESS: Sorry about that. Is
7 that better?

8 THE VIDEOGRAPHER: That's great. It's
9 just if you --

10 THE WITNESS: Thank you. Thanks for
11 letting me know.

12 BY MR. ROTMAN:

13 Q. Have you ever implanted a Bard
14 Recovery filter?

15 A. In the past, no, I don't believe I've
16 used the Recovery personally.

17 Q. Have you ever implanted a Bard G2
18 filter?

19 A. Yes.

20 Q. How many?

21 A. I would have to only estimate. I
22 would say ten to a dozen.

23 Q. And have you ever retrieved a Bard
24 Recovery filter?

1 A. Yes. And perhaps one-third of the
2 previous number?

3 Q. So the number would be what?

4 A. Say three to four filters, from
5 memory.

6 Q. So you've retrieved about three
7 Recoveries in your career?

8 A. Again, this would be based on memory
9 from years back.

10 Q. You've implanted no Recoveries, and
11 retrieved approximately three, from your memory,
12 from years back, correct?

13 A. Well, I think you asked the question
14 of me, if I'm correct, about G2 filters, is that
15 true?

16 Q. Let's just make it clear since there's
17 some confusion. Let's just talk about Recovery
18 for now.

19 A. Okay.

20 Q. You've never implanted a Recovery
21 filter, correct?

22 A. From memory, I don't remember
23 Recovery. And I don't remember having retrieved
24 a Recovery.

1 Q. Okay. So now let's go to the G2.

2 Have you implanted a G2; and if so,
3 how many?

4 A. Yes. And again, it would be by memory
5 an estimate. A dozen or more.

6 Q. And how many have you retrieved, if
7 any?

8 A. By memory, four filters or more.

9 Q. And have you seen any fractures in any
10 of the patients where you've either implanted or
11 retrieved a G2?

12 MR. BROWN: Object to the form. Asked
13 and answered.

14 A. I believe I answered that question.
15 From memory, I don't remember having seen that.
16 BY MR. ROTMAN:

17 Q. And I understand you've never seen a
18 fracture of a Bard Recovery filter in your own
19 patients -- sorry. Strike that.

20 You have seen Recovery fractures from
21 patients of other physicians in your hospital?

22 A. Well, of colleagues in general.

23 Q. Colleagues.

24 How many?

1 A. From memory, over the years, I can say
2 that perhaps one or two cases were shown as
3 examples by colleagues.

4 Q. Other than fracture, do you consider
5 tilt to be a complication?

6 A. I consider tilt to be one aspect of
7 many types of vena cava filters.

8 Q. I'm asking if you consider a tilt of
9 any filter to be a complication.

10 A. I do not consider it to be a
11 complication unless there is an adverse event
12 with symptoms or signs in that particular
13 patient.

14 Q. And do you consider a perforation to
15 be a complication of an IVC filter?

16 A. A perforation, if it is of a moderate
17 to severe nature, and where there are either
18 adverse symptoms or signs in that patient would
19 be considered a complication.

20 Q. So if there's no symptoms or signs in
21 conjunction with a moderate to severe
22 perforation, you do not consider that to be a
23 complication of the filter?

24 A. I would say that specifically and in

1 the literature, penetration that is 3
2 millimeters or less is usually defined as
3 different from perforation greater than 3
4 millimeters. So that if there were to be, for
5 example, a moderate perforation but the patient
6 had no adverse events, had no symptoms, we could
7 say that that was an image-identified
8 complication, but was not, obviously, a
9 symptomatic complication for that patient
10 because they had no adverse outcome.

11 Q. But you would consider it to be a
12 complication of the device?

13 MR. BROWN: Object to form.

14 A. We could put it into that category,
15 yes.

16 BY MR. ROTMAN:

17 Q. If it's a moderate to severe
18 perforation without symptoms?

19 A. Correct, as compared to the more minor
20 degree of a penetration.

21 Q. And have you ever seen a perforation
22 of a Bard recovery filter?

23 A. I've seen them in cases, and displayed
24 at medical meetings, and talked about with

1 colleagues.

2 Q. How many perforations of Bard Recovery
3 filters have you seen?

4 A. Overall in the whole group?

5 Q. Bard Recovery.

6 A. Yes, in your question, Counselor, so
7 that I can understand --

8 Q. How many Bard Recovery filter
9 perforations have you seen?

10 A. When you say when I've seen, I assume
11 you mean overall. And I would say that at
12 scientific meetings, with colleagues, and just
13 from practice experience, I have had a chance to
14 see, that is see described, approximately five
15 to six perforations.

16 Q. And how many in your own patients?

17 A. In my own patients, I remember one.

18 Q. So now we've got, I want to talk about
19 -- do you consider a tilt without symptoms to be
20 a complication of the device?

21 A. I do not consider that to be a
22 complication because, as you know, tilt can be
23 shown both in Bard devices and in other IVC
24 filters, and may be of no clinical significance

1 for the patient.

2 Q. Well, that same explanation would
3 apply to a fracture, correct?

4 A. It would if the fracture were
5 identified by imaging alone, and the patient had
6 no signs and no symptoms.

7 Q. So if you -- you would not consider
8 that to be a complication of the device?

9 MR. BROWN: Object to the form.

10 A. To be fair to your question, I would
11 consider that to be a complication which has
12 been identified by imaging.

13 BY MR. ROTMAN:

14 Q. Yes.

15 And so, have you ever seen a Bard
16 Recovery tilt complication?

17 MR. BROWN: Object to the form.

18 A. I have seen Bard Recovery filter
19 tilting, yes.

20 BY MR. ROTMAN:

21 Q. How many times?

22 A. I would estimate approximately three
23 times.

24 Q. Have you ever implanted a Bard G2X?

1 A. To be fair to your question, I would
2 actually have to look back to records, because I
3 don't hold that in memory, whether the
4 particular filter was a G2X or a G2. And I
5 would say that I really can't give you, to be
6 fair, I can't give you an accurate answer to
7 that question at this moment.

8 Q. Have you ever retrieved a G2X?

9 A. Really, the same answer to that.

10 Q. Have you ever implanted a Bard
11 Eclipse?

12 A. Yes.

13 Q. How many?

14 A. For that filter, which is a more
15 modern device, I would estimate 50 or more.

16 Q. About how many filters do you implant
17 in a given year?

18 A. The number of filters will vary per
19 year, as it does per month. For myself, it
20 might be between 30 and 40 devices in a year,
21 depending on the particular year.

22 Q. And that would be all filters, all
23 manufacturers combined?

24 A. That's correct, all types.

1 Q. Do you know what period of time the
2 Eclipse was on the market?

3 A. The Eclipse was on the market in the
4 period around 2008 to 2009, and I could not give
5 you an exact date range.

6 Q. Do you know what period of time, you
7 know, whether it was a year or two years,
8 three years, that the Eclipse was on the market?

9 A. Well, the Eclipse was not on the
10 market, as I understand it, for a long period of
11 time because there was the next iteration, the
12 Meridian, that was introduced by Bard, and that
13 filter was the device that we had subsequently
14 used.

15 Q. So the answer to my question is? Was
16 it one years, two years, three years, do you
17 know?

18 A. For the Eclipse?

19 Q. Yes.

20 A. My impression from memory is that the
21 Eclipse was in clinical use between a year and
22 two years, as an estimate.

23 Q. In that one to two years where you
24 would have implanted 30 to 40 filters of all

1 manufacturer types per year, you implanted 50 or
2 more Eclipse devices?

3 MR. BROWN: Object to the form.

4 A. I'm sorry, I don't understand your
5 question.

6 MR. ROTMAN: Could you reread it,
7 please?

8 (Whereupon, the reporter read back the
9 pending question.)

10 MR. BROWN: Same objection.

11 A. Well, I think that we're having a
12 misunderstanding on the wording of the question.
13 So when you had asked me how many Eclipse
14 devices have you implanted, I gave you from
15 memory an estimate number. Okay. And the exact
16 number, to be fair, I would have to go back and
17 check records.

18 BY MR. ROTMAN:

19 Q. Your estimate was 50. I didn't
20 misstate that, right? That was what you
21 testified as your estimate, right?

22 A. That was my approximation.

23 Q. And how many Eclipses have you
24 retrieved?

1 A. Again, from memory as an
2 approximation, eight or more filters.

3 Q. And have you ever had a patient with
4 an Eclipse complication?

5 MR. BROWN: Object to the form.

6 A. Personally, no.

7 BY MR. ROTMAN:

8 Q. And have you ever implanted a
9 Meridian?

10 A. By memory, and to the best of my
11 recollection, yes.

12 Q. Approximately how many?

13 A. Again, the exact number would be
14 something I would have to check records. I
15 would say, as an estimate, 20 or more devices.

16 Q. What records would you be able to
17 check to give you the information about the
18 number of Meridians that you've implanted?

19 A. Well, that would be challenging,
20 because one would have to go back to either
21 medical records, specific patient records, or
22 perhaps even consult the company if there were a
23 product use invoice slip sent.

24 Q. How many Meridians have you retrieved?

1 A. Again, as an estimate, six or more
2 devices.

3 Q. And have you ever seen a Meridian
4 complication among your own patients?

5 MR. BROWN: Object to the form.

6 A. Personally, let's see, yes, I've seen
7 a case in which in my own patients there was not
8 a complication but there was, due to the
9 indication for use in the superior vena cava,
10 the arm processes not being in standard position
11 within the vena cava.

12 BY MR. ROTMAN:

13 Q. Do you consider that to be a
14 complication of the device?

15 MR. BROWN: Object to the form.

16 A. No, simply because the patient had
17 severe embolus within the SVC, and was in a
18 state where she might have died within the next
19 two to four hours, and so the filter actually
20 was lifesaving.

21 BY MR. ROTMAN:

22 Q. Have you ever implanted a Denali?

23 A. Yes.

24 Q. How many?

1 A. Again, as an estimate, 50 or more
2 devices.

3 Q. And have you ever retrieved a Denali?

4 A. Yes. And I would say the estimate
5 there would be six or more devices.

6 Q. And have you ever seen a Denali
7 complication?

8 MR. BROWN: Object to the form.

9 A. Personally, no.

10 BY MR. ROTMAN:

11 Q. Have you ever conducted a study of the
12 patients in any of the hospitals where you
13 worked to assess the complications in IVC
14 retrievable filters in those patient
15 populations?

16 A. I've participated in studies with IVC
17 permanent filters, but not retrievable ones.

18 Q. And have you ever proposed a study of
19 retrievable filters in any of the hospitals in
20 which you have been a staff radiologist to
21 assess the status of the filters implanted in
22 the patients in that institution?

23 MR. BROWN: Object to the form.

24 A. By the question, study, you're

1 mentioned as compared to there being only one
2 that must explain all fractures?

3 A. My own personal opinion is that I have
4 not yet encountered an explanation which has
5 weight of evidence behind it. Whether it is
6 connected with one factor or multifactorial, I
7 really can't say. What I can say is it's my
8 opinion that there has not been a mechanism
9 which has yet been proven by the persons who
10 have advanced it.

11 Q. When you say "proven," what level of
12 certainty does it take in your -- according to
13 your own standards that you're applying here to
14 say something is proven?

15 MR. BROWN: Object to the form.

16 A. That's a difficult question, only
17 because proof varies scientifically. For
18 example, we could go back to some of Koch's
19 postulates -- that's spelled K-O-C-H -- in
20 which, medically speaking, if you have an
21 offending agent, the methodology is to identify
22 the offending agent, show that it causes a
23 problem in the human, then take the offending
24 agent and reintroduce it into the human and

1 A. I would say that the one that would
2 fit for me --

3 MR. BROWN: Just object to the form.
4 You can answer.

5 A. The one that would fit for me would --
6 in consideration of the fact that this involves
7 many patients, many devices which have already
8 been implanted, and the protection against a
9 very fearful disease, that is pulmonary embolus,
10 that I would look for evidence where I felt
11 certain beyond any reasonable doubt.

12 BY MR. ROTMAN:

13 Q. And is that the kind of evidence that
14 you're applying for your opinions in this case?

15 A. Overall, yes.

16 Q. And on the issue of explanations for
17 why the Bard retrievable filters fracture, are
18 you aware of what steps Bard has taken to answer
19 that question?

20 A. Yes, I know that Bard has improved,
21 honed, and refined its various newer devices as
22 time has progressed.

23 Q. But I'm asking a different question.
24 I'm asking, what has Bard done to figure out why

1 and observe that there was a fracture. They
2 observed a trend, but there's no way of knowing
3 when the fracture occurred, and if in that
4 particular patient the fracture occurred on day
5 two after it was implanted, or if it occurred on
6 the day before the filter was removed when they
7 observed it.

8 So my own opinion is that further work
9 has to be done on this particular subject before
10 I'm convinced of that direct relationship.

11 Q. And again, you're using the word
12 "convinced." Yes?

13 A. Yes.

14 Q. And this opinion of yours that more
15 work needs to be done, you have not done that
16 work yourself, have you?

17 A. No, I have not done it personally.

18 Q. You have not done any studies to
19 evaluate whether the risk of complications
20 increases with the increased duration of a
21 filter being implanted, a Bard retrievable
22 filter being implanted in a patient?

23 A. No, I haven't performed those specific
24 research studies.